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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,640	03/05/2002	James D. Marks	407T-897221US	1369

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EXAMINER	
SANG, HONG	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/092,640	MARKS ET AL.	
	Examiner	Art Unit	
	Hong Sang	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21,22,24-26,28,41 and 45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21, 22, 24-26, 28, 41 and 45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RE: Marks et al.

1. Applicants' petition to accept unintentionally delayed priority claim under 37 C.F.R. §1.78(a)(3) filed on 3/29/06 was granted on 9/18/06.

2. Applicant's response filed on 3/29/2006 is acknowledged. Claims 21, 22, 24-26, 28, 41 and 45 are pending. Claims 1-20, 23, 27, 29-40, 42-44, and 46-50 are cancelled. Claims 1, 26, 28, 41 and 45 are amended.

3. Claims 21, 22, 24-26, 28, 41 and 45 are under examination.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Objections Withdrawn

5. The objection to the specification as the specification is not updated to reflect current status of the priority documents is withdrawn in view of applicant's amendment to the specification.

6. The objection to claims 46 and 47 because they are duplicates of claim 45 is withdrawn in view applicant's cancellation of claims 46 and 47.

7. The objection to claim 27 because the word "the" is duplicated is withdrawn in view of applicant's cancellation of claim 47.

Rejections Withdrawn

8. The rejection of claim 21, and its dependent claims 22-27, claim 41 and its dependent claims 45-47 under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of applicant's amendment to the claims to recite "an isolated" nucleic acid.

9. The rejection of claims 21 and its dependent claims 22-27, claim 28, claims 41 and its dependent claims 45-47 under the second paragraph of 35 U.S.C. 112 as vague and indefinite for reciting the term "C6 antibody" and "C6.5 antibody" as the sole means of identifying the claimed molecule is withdrawn in view of applicant's amendment to the claims to recite specific SEQ ID NOS to identify the claimed molecule.

10. The rejection of claim 28 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement because the claim read on a cell within a transgenic animal is withdrawn in view of applicant's amendment to the claim to recite an "isolated cell".

11. The rejection of claim 23 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement because the is drawn in part to a nucleic acid encodes an antibody having a V_L or V_H CDR3 domain is withdrawn in view of applicant's cancellation of the claim.

12. The rejection of claims 21-22, 28, 41, 45-48 under 35 U.S.C. 103(a) as being unpatentable over US patent NO: 6,165,464 (earliest filing date is at least 1/25/1988) in combination of the teaching of Wels et al. (J. Steroid Biochem. Mol. Biol. 43 (1-3): 1-7) and Marks et al. (Biotechnology 10: 779-783, 1992, IDS) is withdrawn in view of applicant's amendment to the claim to recite the SEQ ID NO. 32 and SEQ ID NO. 36.

Rejections Maintained

13. The rejection of claims 21-22, 24-26, 28, 41, and 45 under 35 U.S.C. 102(a) as being anticipated by Schier et al. (Immunotechnology 1:73-81, 1995) is maintained.

The response states that the present applicant claims priority to June 14, 1995, less than 1 year prior to Applicants filing date. Upon a showing of otherwise allowable subject matter, applicants will provide Declarations in accordance with *In re Katz,* signed by the inventors of the present application, establishing that the Schier et al. article describes Applicants' own work and thereby obviate this reference.

Since applicants have not submitted the Declarations to overcome the rejection, the rejection is maintained.

New Grounds of Objections and Rejections

Claim Objections

14. Claim 28 and 45 are objected to because claims depend upon the cancelled claim 29.

15. Claim 45 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claim 45 has not been further treated on the merits.

Claim Rejections - 35 USC § 112, 1st paragraph

16. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

17. Claims 21, 22, 24, 25, 28 and 45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding a human C6 antibody that specifically binds to C-erbB-2, wherein said C6 antibody comprises the variable heavy (V_H) chain of C6.5 (SEQ ID NO.32) and the variable light (V_L) chain of C6.5 (SEQ ID NO.36), does not reasonably provide enablement for an isolated nucleic acid encoding a human C6 antibody that specifically binds to C-erbB-2, wherein said C6 antibody comprises the variable heavy (V_H) chain of C6.5 (SEQ ID NO.32) or the variable light (V_L) chain of C6.5 (SEQ ID NO.36), the nucleic acid of claim 21, wherein said nucleic acid encodes the variable light (V_L) chain of C6.5, and the nucleic acid of claim 21, wherein said nucleic acid encodes the variable heave (V_H) chain of C6.5. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 21, 22, 24, 25, 28 and 45 are drawn in part to a nucleic acid encodes an antibody having a V_L or V_H, an isolated cell comprising said antibody and an expression cassette comprising said nucleic acids.

It is well established in the art that the formation of an intact antigen-binding site generally requires the association of the complete heavy and light chain variable regions of a given antibody, each of which consists of three CDRs which provide the majority of the contact residues for the binding of the antibody to its target epitope. The amino acid sequences and conformations of each of the heavy and light chain CDRs are critical in maintaining the antigen binding specificity and affinity which is characteristic of the parent immunoglobulin. It is expected that all of the heavy and light chain CDRs in their proper order and in the context of framework sequences which maintain their required conformation, are required in order to produce a protein having antigen-binding function and that proper association of heavy and light chain variable regions is required in order to form functional antigen binding sites. Even minor changes in the amino acid sequences of the heavy and light variable regions, particularly in the CDRs, may dramatically affect antigen-binding function as evidenced by Rudikoff et al (Proc Natl Acad Sci USA 1982 Vol 79 page 1979). Rudikoff et al. teach that the alteration of a single amino acid in the CDR of a phosphocholine-binding myeloma protein resulted in the loss of antigen-binding function. It is unlikely that antibody having just a V_L or V_H as defined by the claims have the required binding function. The specification provides no direction or guidance regarding how to produce the full scope of antibodies as broadly defined by the claims, i.e. an antibody having just

a V_L or V_H chain that have binding activity. Undue experimentation would be required to produce the invention commensurate with the scope of the claims from the written disclosure alone. Further, the specification does not teach that a functional human antibody having just a V_H or V_L. Panka et al (Proc Natl Acad Sci USA Vol 85 3080-3084 5/88) demonstrate that a single amino acid substitution of serine for alanine results in decreased affinity.

In at least one case it is well known that an amino acid residue in the framework region is involved in antigen binding (Amit et al Science Vol 233 747-753 1986).

One of skill in the art would neither expect nor predict the appropriate functioning of the antibody as broadly as is claimed. Therefore, in view of the lack of guidance in the specification and in view of the discussion above one of skill in the art would be required to perform undue experimentation in order to practice the claimed invention

Conclusion

18. No claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hong Sang, Ph.D.
Art Unit 1643
October 10, 2006

CHRISTOPHER H. YAEN
PRIMARY EXAMINER